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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,781	02/06/2006	John L Zenk	HUM251USPTO 2	1677

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EXAMINER	
ROGERS, JUNE MARIE	
ART UNIT	**PAPER NUMBER**
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,781	ZENK, JOHN L	
	Examiner	Art Unit	
	JUNE ROGERS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :10/26/2005, 10/31/2007, 12/11/2007.

DETAILED ACTION

Priority

This application claims priority to US provisional application 60,439,816 filed on January 13, 2003. Applicants' priority is acknowledged.

Obviousness-type Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 7199116. Although the conflicting claims are not identical, they are not patentably distinct from each other. In US Patent No. 7199116, the claims are directed to a method of modulating the

metabolism of a dieting mammal using 7-oxo-DHEA as a "metabolic modulating agent." Applicants' current application is directed to a method of achieving accelerated weight loss by administering a "weight-loss accelerating agent" which is 7-oxo-DHEA. Any compound that has the effect of modulating the metabolism of a dieting mammal would also have the effect of inducing weight loss. Furthermore, the same active agent is being used in both methods and all properties of the active agent would be necessarily present in the compound (weight loss accelerating and metabolism modulating); therefore claims 1-9 of Application No. 10, 541,781 are not patentably distinct over claims 1-9 of US Patent No. 7199116.

Provisional Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-9 of copending Application No. 10541780. This application contains a method for achieving accelerated weight loss and copending Application No. 10541780 is directed to a method of achieving fat loss. However, the patient population and active agent (s) are identical and thus one would expect both weight loss and fat loss. Therefore the claimed inventions are of the same scope. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Kalman et al (Current Therapeutic Research, vol. 61, No. 7, 2000). Kalman et al. discloses administration of 100 mg capsules of 3-Acetyl-7-oxo-dehydroepiandrosterone twice daily, in a double- blind, placebo-controlled protocol to subjects following a reduced calorie diet (abstract). Kalman et al. teaches that 3-Acetyl-7-oxo-dehydroepiandrosterone is a pro-drug of 7-oxo-DHEA and has no androgenic activity (page 436, lines 5-7). In this study, the group receiving the 3-Acetyl-7-oxo-dehydroepiandrosterone supplements rate of weight loss was 1.4kg per week versus <0.5kg in the placebo group. (p. 440, lines17-18). Kalman et al. postulated that this

difference was due to the efficacy of 3-Acetyl-7-oxo-dehydroepiandrosterone to increase weight loss (p. 440, lines 18-20). Kalman et al. concluded that 7-oxo-DHEA combined with a reduced calorie diet significantly reduces body weight and fat (p.436, conclusion section).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partridge et al (U.S. Patent No. 5,296,481) in view of Serdula et al. (American Journal of Public Health 1994, Vol. 84, No.11-abstract).

Partridge et al. teaches that Δ5-Androstenes substituted at c-3, c-7, and /or c-17 with a hydroxyl or a keto group are biologically effective for controlling weight gain and promoting weight loss (column 2, lines 20-24). Patridge et al. discloses a method for controlling weight gain and/or promoting weight loss by daily oral administration in human subjects of 7-oxo-DHEA ((Δ5-Androstene-3-ol-7, 17-dione) and the derivatives thereof wherein the 3 hydroxyl group is esterified with an acid (column 1, lines 52-68; column 2, lines 1-5 and claims 16, 17). Patridge et al. teaches these compounds are not capable of inducing the synthesis of sex hormones (column 1, lines 55-56).

Partridge et al. does not specifically teach that substituted Δ5-Androstenes should be administered to a “dieting mammal” as defined in the specification on page 2, paragraph 0007, as eating and drinking sparingly with the intent to lose weight.

Serdula M et al. teaches that those who are trying to lose weight consume fewer calories as well as take special supplements to control their weight (abstract). Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to administer the weight loss supplements taught Partridge, which are biologically effective for controlling weight gain and promoting weight loss, to a dieting person because dieters take special supplements to assist in control of their weight.

Applicant's recitation in the claims of the expression "fat loss accelerating agent" would be an obvious inherent property of the compounds taught by the prior art since the prior art teaches the same active agents, therefore any property (fat loss accelerating) of these compounds would be necessarily present in the cited reference.

Conclusion

No claims allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JUNE ROGERS whose telephone number is (571)270-3497. The examiner can normally be reached on M-F 9-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fred Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Juné M. Rogers

/Barbara P. Badio, Ph.D./
Primary Examiner, Art Unit 1612